Christopher P. Molineaux – President & CEO, Life Sciences Pennsylvania, USA



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Christopher P. Molineaux of Life Sciences Pennsylvania outlines the Keystone State's rich lineage of pharmaceutical innovation, how the association is building inter-state and international connections, and why Philadelphia is justified in branding itself as the 'Cellicon Valley'.

Life Sciences Pennsylvania represents the full spectrum of life sciences, including biotech, medtech, pharma, and CROs. In terms of your membership base, which elements are growing most quickly?

The fastest growing section of our membership is small biotech companies – although this now refers more to these companies' start-up business models than their strict focus on biologics. We have 842 members in our association, 60 percent of which are R&D-based companies ranging from pharma, biotech, medical devices, diagnostics, investment organizations that have R&D-based companies in their portfolios, digital health companies, and certain types of CROs. From that pool of companies, 75 percent – around 300 – have 10 employees or fewer and are small start-ups just getting off the ground.

How are you able to manage and represent such a diverse group of companies across the entire healthcare value chain?

We have subcommittees to align interests, including a state policy committee of 45 people that meets monthly and each year determines our advocacy priorities. We have a federal policy committee that helps us with our policy agenda at the national level, a medical device committee and so on. These are all advisory committees which exist along with the typical governance committees such as the executive and compensation committees. Our advisory committees drive the programmes that we hold and the advocacy activities we conduct.

How important are CROs to Life Sciences Pennsylvania?

We are the only state to have a partnership with the Association of Clinical Research Organizations (ACRO). ACRO has 19 members, whereas we have 56 CROs in our membership. At the state level, we have more than they have nationally.

Many of the smaller CROs are performing one function only in the development process. Many Big Pharma employees were let go because their functions could be outsourced. Therefore, these people have left and formed their own organizations to perform that same function.

How do you and your members currently view the work being carried currently by the FDA?

The FDA has improved a great deal and, after a considerable amount of reform, have become very open to very expensive and high-risk therapies. Our member companies' CEOs consider the FDA to be a very important and valuable partner. 'Partnership' may seem a strange word to describe the relationship between the regulator and private companies, but it is apt. Our companies work well with the FDA and the FDA works well with them.

In which areas do your member companies wish to see further improvement from the FDA?

Transparency and communication can always be improved. A lot of this is personality driven. One individual within the FDA may be excellent to work with and keep you up to date on your filing,

while another may not give you that information and reject your application without giving a clear reason why. This situation has befallen several of our member companies.

The Trump administration has cut corporate tax by 20 percent. How do your member companies feel about it – is it business as usual or does it make a big difference?

It makes an enormous difference! The cut in corporate and income tax has meant some relief in terms of companies being able to repatriate revenue that was generated overseas. That is now being reinvested. Our member companies have been able to hire more people and invest more in R&D which benefits everybody – the companies, the marketplace, and ultimately the patients who use the drugs produced.

How do you collaborate with other states?

Our primary focus has to be at the state level. That is what our mission is all about – to make Pennsylvania the most attractive place from a policy and business standpoint to start a company. However, no state works in a bubble and the national policy agenda also has an impact. Therefore, we often partner with other state associations such as New Jersey, Delaware, Massachusetts and California, as well as national trade associations like BIO, ACRO and PhRMA to influence Congress and the Trump administration.

What about internationally?

We now have seven international partnerships – with the Lithuanian Biotechnology Association, Assobiotec Italia, the Taiwan Bio Industry Organization, One Nucleus in the UK, the Montreal Invivo and Quebec International, the Indo-US Science and Technology Forum in Delhi, India, and Karnataka Biotechnology and Information Technology Services, also in India.

Through these agreements, if, for example, a Pennsylvania company is hoping to do business in Bangalore, we can connect them with our partner in Karnataka.

Many of the pharma executives outside the USA we speak to want to open offices in the US. Is there still space for all of them? How do the Americans feel about more

companies coming in to market their drugs?

If you are talking about a company that is going to bring the 20th statin to the marketplace, we probably don't need them. However, if a company is bringing a new or transformational technology or way of treating a disease, then we would welcome them. There are literally thousands of rare diseases in the world and in the USA that do not currently have any medical answer. We would welcome any company that helps address that.

From an economic, job creation and patient benefit standpoint, this investment is positive.

Because the US is a free-market system rather than a government-controlled one, as long as companies operate legitimately and ethically, they can grow and succeed; something that is not always possible in their home markets.

Asian companies tend to look to California when expanding into the US, while Europeans often head to Boston. How can you convince these firms of the benefits of investing in Pennsylvania?

Firstly, we are not in the business of business attraction, that's not what a trade association does. However, we advocate for policies that make Pennsylvania attractive. For example, the state has an R&D tax credit programme. For each of the last eight years, there has been a state bucket of USD 55 million dollars in tax credits that companies can take advantage of when they are investing in R&D. Other states also offer this incentive, in varying amounts.

As 'The Keystone State', we also have 'Keystone Innovation Zones' – geographic areas that are tax-free for start-up companies for ten years. These locations are determined based on where a lot of companies already exist.

Furthermore, Pennsylvania is a lot less expensive and the cost of real estate more manageable than Boston.

Philadelphia is equidistant from the financial markets in New York and the regulatory agencies in Washington – about one hour and half from each.

There is a deep legacy of large pharma companies here in Philadelphia as well, dating back to the very first college of pharmacy, which is in Philadelphia – the University of the Sciences. Graduates from this university who built their legacy here include Eli Lilly and his father, Silas Burroughs and Henry Wellcome of Burroughs-Wellcome, Robert McNeil, and John Wyeth.

Is Pennsylvania a state with a net inflow or outflow of talent? How does this affect recruitment?

There was an outflow problem in the past but, more recently, that has turned around. Talent from the local universities is now more likely to stay and work in Philadelphia than in the past.

Pennsylvania has two of the top five universities in the country for National Institutes of Health (NIH) research funding – the University of Pennsylvania is number four and the University of Pittsburgh is number five. This state and region have a lot of advantages that we don't always necessarily get credit for.

How is Philadelphia and Pennsylvania positioning itself globally when is related to the new emerging trends in pharma and biopharma?

The industry and medicine as a whole is headed towards cell and gene therapy and precision medicine. It is important to point out that that started here. The first ever cell therapy to be approved in the USA was from a Pennsylvania company that was spun out of the University of Pennsylvania. The first gene therapy – Spark Therapeutics' LUXTURNA – was spun out of the Children's Hospital of Philadelphia.

20 years ago, Bill Kelly, then dean of the School of Medicine at Penn, put together a strategy for moving into cell and gene therapy. He has built something of a family tree of people and companies in Philadelphia that have done that. Philadelphia is home to Spark, TMunity, Carisma Therapeutics, Absorption Systems (a CRO involved in cell and gene therapy), WuXi Apptec's US headquarters, Aro Biotherapeutics – the list goes on.

There are now more than 70 individual labs in the Philadelphia region that are focused on cell and gene therapy. More than USD one billion has already been invested in advanced manufacturing for cell and gene therapy in the Philadelphia region. We are at the epicentre of cell and gene therapy, what we are calling 'Cellicon Valley'. Nowhere else boasts such a concentration of cell and gene therapy manufacturing expertise in one place.

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